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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,055	11/17/2003	Gerald Cagle	1732 US F2	3314

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,055	CAGLE ET AL.	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-10 are presented for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102 (b) as being anticipated by Peterson et al. (U.S. patent 5,607,942). Peterson et al. teach the use of the claimed antibacterial agent in a pharmaceutical formulation for the treatment of ophthalmic infection. See column 54, line 22. The above reference makes clear that the claimed composition and the use thereof are old and well known.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-7 and 9-10are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (5,607,942) in view of Cagle et al. (WO 90/01933) and Bergamini et al. (5,597,560).

Petersen et al. Teach the use of the claimed antibiotics for ophthalmic use. See column 54, line 22. The above reference differs from the claimed invention in the presence of steroidal or non-steroidal anti-inflammatory agent. Cagle et al. Teach the use of quinoline antibiotics in combination with steroidal anti-inflammatory agents. Bergamini et al. Teach the use of antibiotics with non-steroidal anti-inflammatory

agents. See column 2, lines 37-60. It would have been obvious for a person skilled in the art to add a steroidal or non-steroidal anti-inflammatory agent to the claimed antibiotics, considering that the secondary references teach the addition of anti-inflammatory agents to antibiotics for the treatment of inflammation associated with infection is old and well known.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed antibiotics for the treatment of ophthalmic infection and the others relate to the use of antibiotics in combination with combination with steroidal and non-steroidal anti-inflammatory agents for the treatment of inflammation associated with infection as old and well known. It would have been obvious to a person skilled in the art to substitute one antibiotic for another and use it with anti-inflammatory agents. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 2-7 and 9-10 are properly rejected under 35 U.S. C. 103.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,716,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap. The claims of the instant application are drawn to a group of quinoline antibiotics encompassing moxifloxacin claimed in the U.S. Patent application. The claims of the instant application also include the addition of steroidal or non-steroidal anti-inflammatory agents to the quinoline antibiotics.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of ophthalmic, otic or nasal infection, does not reasonably provide enablement for preventing ophthalmic, otic or nasal infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112 first paragraph, have been described in In re Wands, 8USPQ 2d 1400 (Fed. Cir. 1988). Among these factor are:

(1) The nature of the invention:

The claims are drawn to a method of treating or preventing ophthalmic, otic or nasal infection.

(2) The sate of the prior art:

The state of the art does not recognize that the prevention of infections is easily accomplished.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

(5) The breadth of the claims:

The claims are very broad and encompass the prevention of ophthalmic, otic or nasal infection.

(6) The amount of direction or guidance presented:

Applicant's specification provides no guidance for the prevention of ophthalmic, otic or nasal infection.

(7) The presence or absence of working examples:

There are no examples in the specification directed to the prevention of ophthalmic, otic or nasal disorders.

(8) The quantity of experimentation necessary:

Since the activity of the claimed compounds for the prevention of ophthalmic, otic or nasal disorders must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with

undue experimentation to determine ophthalmic, otic and nasal infections, which can be prevented with the claimed compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F